

Certificate of facsimile transmission for Supplemental IDS, Remarks
Accompanying Supplemental IDS for application 10/037,718 and Declaration of
Inventor R.E. McGinnis. Submitted by fax to USPTO at 571-273-8300

**RECEIVED
CENTRAL FAX CENTER**

NOV 18 2005

Certificate of Facsimile Transmission

The following documents were submitted by facsimile today, November 18, 2005
by me, Robert O. McGinnis to the USPTO. These documents were faxed to 571-
273-8300 by me.

The documents are as follows:

- 1) Supplemental Information Disclosure Statement for application 10/037, 718
(including 1 sheet modified Form PTO/SB/08B) a total of 3 pages (signed).
- 2) Remarks Accompanying the Supplemental Information Disclosure Statement
(2 pages, signed)
- 3) Declaration of Inventor R. E. McGinnis (2 pages, signed).

Total Sheets (or pages), including this Certificate of Facsimile Transmission, 8
sheets.



Robert O. McGinnis
Agent of Record
Reg. No. 44, 232
Ph. 406-522-9355

Supplemental Information Disclosure Statement regarding U.S. Application No. 10/037718, Title of the Invention: Two-Dimensional Linkage Study Methods and Related Inventions. November 17, 2005 Atty's Docket No. 2DLSM&R12/01
1 of 2 (Submitted by fax to 571-273-8300)

In the United States Patent and Trademark Office

In re application of:

Inventors: MCGINNIS, Ralph Evan and
MCGINNIS, Robert Owen

Title of the Invention: "Two-Dimensional Linkage Study Methods and Related Inventions."
U.S. Application No. 10/037718
Date of filing: 04 January 2002

Examiner Kenneth R. Horlick, Art Unit 1637

Patent application 10/037718 is a continuation-in-part of U.S. Patent Application 09/947,768 (filed 5 SEPT 2001), now abandoned. And 09/947,768 claims priority from US Provisional 60/230570 (filed 9/5/2000). Patent Application 09/947,768 is a continuation-in-part of U.S. Patent Application 09/623,068 (filed 26 AUG 2000). The present patent application is also a continuation-in-part of Patent Application 09/623,068 (filed 26 AUG 2000). Application 09/623,068 claims priority from PCT/US99/04376 filed (2/26/99). PCT/US99/04376 claims priority from US Provisional applications: 60/076182 filed 27Feb1998, 60/086947 filed 27May1998, 60/076102 filed 26 Feb 1998 and 60107673 filed 7 Nov 1998.

Supplemental Information Disclosure Statement

c/o Honorable Commissioner of Patents
Fax number 571-273-8300

Sir:

This submission is a supplemental IDS. A Request for Continuing Examination (RCE), has been recently filed, so no fee is due from the applicants. Attached hereto is an amended version Form PTO/SB/08B (1 sheet) listing one document believed relevant to the subject application. The form has been amended by eliminating the words "OTHER PRIOR ART" from the listing heading. This was done to signify that no reference in this Supplemental IDS is admitted by the applicants to be prior art with respect to the invention by the reference's listing in the IDS.

Supplemental Information Disclosure Statement regarding U.S. Application No. 10/037718, Title of the Invention: Two-Dimensional Linkage Study Methods and Related Inventions. November 17, 2005 Atty's Docket No. 2DLSM&R12/01
2 of 2 (Submitted by fax to 571-273-8300)

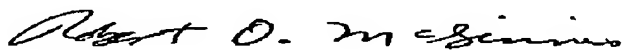
The single document listed on Amended Form PTO/SB/08B is labeled "BB", so as to follow the last document submitted in the "OTHER ART-NON PATENT LITERATURE DOCUMENTS" section of the previously filed IDS of March 4, 2004. The single document BB is an unpublished manuscript (or version) of the inventor's paper MCGINNIS, R.E. Annals of Human Genetics, volume 62, pp. 159-179, (1998) listed as "Cite no. A" in the previously filed IDS of April 4, 2002 and Amended IDS of March 4, 2004. This document A has already been considered by the Examiner as evidenced by a returned, initialed copy of the previously filed IDS forms. No copy of document BB is included herewith as it is substantively cumulative with document A. And a copy of document A has been previously submitted with a previously filed IDS for the present application. Document A is discussed in the background and specification of the patent application and is incorporated into the application by reference.

A copy of document BB was sent in confidence to Professor Jurg Ott of Rockefeller University between about Oct. 3, 1997 and Nov. 3, 1997 (see Declaration of R. E. McGinnis enclosed herewith). The applicants and inventors, R. E. McGinnis and R. O McGinnis do not consider document BB a "printed publication" under 102(b); (see Remarks Accompanying Information Disclosure Statement). It is respectfully requested that this new document (labeled BB) be considered by the examiner and an initialed copy of Form PTO/SB/08B, with initials next to the reference BB be returned to the undersigned.

This disclosure statement should not be construed as a representation that a search has been made or that no other material information as defined in 37 C.F.R. 1.56 (a) or similar requirements exists.

It is believed that this disclosure complies with the requirements of 37 C.F.R. 1.56, 1.97, 1.98 and the M.P.E.P. 609 and similar requirements. If for some reason the examiner considers otherwise, it is respectfully requested that the undersigned be notified.

Respectfully submitted,



Robert O. McGinnis, Coinventor, Agent of Record and U.S. Patent Agent 44, 232
Address for correspondence: 1575 West Kagy Blvd., Bozeman, MT. 59715, phone 406-522-9355

November 17, 2005

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/037718
		Filing Date	04 JAN 2002
		First Named Inventor	MCGINNIS, R.E.
		Group Art Unit	1637
		Examiner Name	Hoflick, R.
		Attorney Docket Number	2 DL SM & R 12/01
Sheet	1	of	1

OTHER: - - ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BB	Unpublished manuscript of MCGINNIS, R.E., Annals of Human Genetics, vol. 62, pp. 159-179, (1998).	
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Remarks accompanying Supplemental Information Disclosure Statement regarding U.S.
Application No. 10/037718, Title of the Invention: Two-Dimensional Linkage Study
Methods and Related Inventions. November 17, 2005 Atty's Docket No.
2DLSM&R12/01 submitted by fax to 571-273-8300
1 of 3

**RECEIVED
CENTRAL FAX CENTER**

NOV 18 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: MCGINNIS, et al

Attorney's Docket Number: 2DLSM&R12/01

Application No.: 10/037718

Group Art Unit: 1637

Filing Date: January 4, 2002

Examiner: Ken Horlick

**TITLE: TWO-DIMENSIONAL LINKAGE STUDY METHODS AND RELATED
INVENTIONS**

Commissioner for Patents
Fax number: 571-273-8300

REMARKS ACCOMPANYING SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner:

Consideration of the following remarks is respectfully solicited prior to examination.

In his declaration filed herewith the Inventor, R. E. McGinnis, has declared that certain activities took place more than one year before (1) the filing date of this application and (2) some applications of which the benefit of priority is claimed. To ensure full compliance with the duty to disclose information material to patentability, Inventor has declared to the Office, under 37 CFR 1.56, that he sent a copy of an unpublished manuscript of a paper in confidence to a professor. Specifically Inventor R. E. McGinnis, has declared that:

The date of November 7, 1997, referred to herein as the critical date, is more than one year prior to the respective filing dates of the present application and some of the priority applications for the present application. The critical date is exactly one year from the filing date of U.S. Provisional Application No. 60/107,673 (filed November 7, 1998), the benefit of which is claimed by the present application.

The present application claims priority from application No. 09/947, 768 filed September 5, 2001, which claims priority from Provisional Application No. 60/230, 570 filed September 5, 2000. The present application also claims priority from application No. 09/623, 068 filed on August 26, 2000.

The present application also claims priority from International Application PCT/US99/04376, filed February 26, 1999. And PCT/US99/04376 claims priority from four Provisional Applications: U.S. Provisional Application No. 60/076,102 filed February 26, 1998, U.S. Provisional Application No. 60/076,182 filed February 27, 1998, U.S. Provisional Application No. 60/086, 947 filed May 27, 1998 and U.S. Provisional Application No. 60/107, 673 filed November 7, 1998.

Remarks accompanying Supplemental Information Disclosure Statement regarding U.S. Application No. 10/037718, Title of the Invention: Two-Dimensional Linkage Study Methods and Related Inventions. November 17, 2005 Atty's Docket No. 2DLSM&R12/01 submitted by fax to 571-273-8300
2 of 3

Prior to the critical date, I sent a copy of an unpublished manuscript (or version) of the paper that was eventually published by the *Annals of Human Genetics* in 1998 in volume 62 on pages 159-179 (referred to herein as AHG98) to Professor Jurg Ott of Rockefeller University. My best recollection is that I included a letter to Professor Ott with the manuscript (as is customary in the field) indicating that it was still unpublished. Under such circumstances (as is customary in the field) such a manuscript is regarded as confidential. It was my expectation and intent that Professor Ott would, as is customary, treat the manuscript as confidential. Shortly after sending the manuscript to Professor Ott, a similar manuscript was submitted to the *Annals of Human Genetics* for publication; and I requested that the *Annals* make professor Ott a reviewer of the manuscript. I have good reason to believe (although I do not know for sure) that Professor Ott was indeed made a reviewer of the manuscript.

AHG98 was listed as reference A in the original Information Disclosure Statement (filed April 4, 2002) for the present application and a copy of AHG98 was included with the Information Disclosure Statement for priority application 09/623,068 (now abandoned). The manuscript was sent to Professor Ott sometime between about October 3, 1997 and November 3, 1997. A similar manuscript was sent to, and received by, the *Annals of Human Genetics* on about November 3, 1997.

Applicants (and Inventors) R.E. McGinnis and R. O. McGinnis respectfully submit that the unpublished manuscript designated BB herein is not a "printed publication" under 35 USC 102(b). In *In re Wyer* the CCPA set a standard that emphasized dissemination, availability and accessibility in order for a document to qualify as a "printed publication" under 102(b).¹

The District Court in *Hybritech Inc. v. Abbott Laboratories* quoted the standard of *In re Wyer* when it found that a copy of an oral speech (the Ekins speech) that was not distributed and was not made available on request after the speech was not a printed publication.² The Ekins speech was delivered in March of 1979 and matured into a later publication.³ The Ekins speech was presented at an International Symposium in March of 1979 before its publication as part of the Symposium Proceedings.⁴ And the Ekins speech had at least two figures.⁵

¹ "...the one who wishes to characterize the information, in whatever form it may be, as a 'printed publication', should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents." *In re Wyer* 210 USPQ at 795.

² "To constitute a section 102(b) bar, the Ekins speech must be a 'printed publication' available and accessible to persons skilled in the art, *In re Wyer*..... Absent any evidence that the copies were distributed at the speech or made available on request after the speech, I do not believe the Ekins reference amounts to a publication for the purposes of 102(b) as of March 1979." *Hybritech Inc. v. Abbott Laboratories* 4 USPQ 2d at 1006, 1007.

³ "One of the points pursued vigorously by Abbott was a March 1979 speech by Roger Ekins that then matured into a November 1979 publication..... Dr. Sorenson's deposition, however, reveals that he, as the book coordinator of the committee to which Ekins submitted his manuscript, received two copies of the manuscript. In any event, the availability of five documents on this

Remarks accompanying Supplemental Information Disclosure Statement regarding U.S. Application No. 10/037718, Title of the Invention: Two-Dimensional Linkage Study Methods and Related Inventions. November 17, 2005 Atty's Docket No. 2DLSM&R12/01 submitted by fax to 571-273-8300
3 of 3

Similarly in *In re Bayer* a thesis that was uncatalogued, unshelved and inaccessible to the public was not considered a "printed publication" under 102(b) by the CCPA even though copies of the thesis were made available to three members of a graduate committee.⁶

The Inventor's confidential disclosure of the manuscript designated document BB decisively does not meet the dissemination, accessibility and availability standards of a "printed publication" of the *Wyer* or *Byer* cases. Accordingly, the applicants respectfully submit that the manuscript designated document BB does not constitute a printed publication under 35 U.S.C. 102(b).

Respectfully Submitted,



Robert O. McGinnis,
Reg. No. 44, 232
Ph 406-522-9355, November 17, 2005

restricted basis does not amount to publication under 102(b)." *Hybritech Inc. v. Abbott Laboratories* 4 USPQ 2d at 1006, 1007.

⁴ R. Ekins, "Radioassay methods" in "Radiopharmaceuticals II: Proceedings 2nd International Symposium on Radiopharmaceuticals, March 19 to 22, 1979, Seattle, Washington" published in October 1979, Book Coordinator: J.A. Sorenson, Salt Lake City, Utah, USA. (Source: BOARD OF APPEAL OF THE EUROPEAN PATENT OFFICE, Case Number T 0063/94 – 3.3.4 at page 1, Summary of Facts and Submissions; available online as a pdf file at <http://legal.european-patent-office.org/dg3/pdf/t940063eu1.pdf>)

⁵ "In particular, the article discusses solid-phase 'sandwich' or 'two-site' assay methods in which use is made of two separate radioisotopically-labelled antibodies that recognise two different binding sites on the antigen molecule (see, in particular, page 223 and Figure 2)." (Source: BOARD OF APPEAL OF THE EUROPEAN PATENT OFFICE, Case Number T 0063/94 – 3.3.4 at page 8; available online as a pdf file at <http://legal.european-patent-office.org/dg3/pdf/t940063eu1.pdf>)

⁶ "Touchstone in determining whether printed document constitutes publication bar, under 35 U.S.C. 102(b), is public accessibility....we think it is apparent that a printed document may qualify as a 'publication' under 35 USC 102(b), notwithstanding that accessibility is restricted to a 'part of the public,' so long as accessibility is sufficient 'to raise a presumption that the public concerned would know of [the invention]' Accessibility to appellant's thesis by the three members of the graduate committee under the circumstances of the present case does not raise such a presumption. we are unconvinced that appellant's thesis defense before the graduate committee in its official capacity as arbiter of appellant's entitlement to a master's degree was somehow transmuted into a patent-defeating publication merely by depositing the thesis in the university library where it remained uncatalogued and unshelved as of the critical date in question." *In re Bayer* 196 USPQ at 670, 674 and 675.